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| Janet Fowler 3/10/04 | |
| Signature Date | |

PATENT APPLICATION IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| Applicant | : | James A. Hoffmann |) | Confirmation No. 4243 |
|------------|----|--------------------|-----|------------------------------|
| Serial No. | : | 10/072,540 |) | |
| Filed | ; | February 8, 2002 |) | Group Art Unit:1614 |
| For | :. | GLP-1 Formulations |) | Examiner: Delacroix-Muirheid |
| Docket No. | | X-11368A | .) | |

RESPONSE TO RESTRICTION AND/OR ELECTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

An Election Requirement was set forth in an Office Action mailed January 14, 2004, for the patent application captioned above.

Applicant submitted new claims 35-53 in a preliminary amendment dated February 8, 2002. Applicant inadvertently cancelled claims 24-34. Applicant agrees with the Examiner that these claims, 24-34, are not present in this application. Please cancel claims 1-23. Thus, claims 35-53 are the only pending claims in the present application.

Applicant also inadvertently requested priority to AN 09/573,809. Please disregard this priority request. Applicant intended to request priority to the parent case, AN 09/585,181, which WAS filed on June 1, 2000. Therefore, on page 1, lines 5-7, replace:

This application is a continuation of International Application Serial No. PCT/US98/25515, filed December 2, 1998, which claims the benefit of U.S. Provisional Application 60/067,600, filed December 5,1997. The entire teachings of these applications are incorporated herein by reference.

Serial No. 10/072,540

with:

This application is a continuation of co-pending U.S. Serial No. 09/585,181, now U.S. Patent No. 6,358,924, filed June 1, 2000.

The Examiner has grouped claims 1-10 into Group I, claims 11-23, and 53 into Group II, and claims 35-52 into Group III. Applicant has cancelled claims 1-23, therefore the only restriction that remains is between Group II (claim 53) and Group III (claims 35-52). Applicant elects Group III with traverse. Applicant respectfully disagrees with the Examiner in that the method can be practiced with a materially different product such as sulfonylurea compounds or insulin therapy. The product of the Applicant's invention is a specific stable formulation comprising a GLP-I compound. Insulin or sulfonylurea compounds in this specific formulation may not provide the same benefit to a patient. For example, it is known that insulin requires zinc to form hexamers. Applicant's formulation does not require zinc. Also, the use of sulfonylurea compounds have been linked to an increase in morbidity and mortality among patients with diabetes mellitus who suffered myocardial ischemia and infarction. Furthermore, no additional searching should be necessary beyond searching for the specific stable formulation. Applicant submits it would not be an undue burden for the examiner to additionally consider claim 53 that encompasses a method of using the specific stable formulation Application. Thus, Applicant requests that claims 35-52 be examined with claim 53.

If, for any reason, the Examiner feels that a telephone conversation would be helpful in expediting the prosecution of this case, the Examiner is urged to call me.

Respectfully submitted,

Gregory A-Cox
Attorney for Applicants
Registration No. 47504

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Fax

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Date: February 10, 2004

To:

Examiner Delacroix-Muirheid

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Subject: Response to Restriction and/or Election Requirement For 10/072,540

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